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iderson, Farabow,		NGUYEN, DA	VE TRONG
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1300 I Street, N.W. Washington, DC 20005		1632	
	12/07/2001 90 10/03/2003 aderson, Farabow, er, L.L.P	12/07/2001 Patrice Denefle 190 10/03/2003 aderson, Farabow, er, L.L.P	12/07/2001 Patrice Denefle 03806.0529 90 10/03/2003 EXAMI nderson, Farabow, er, L.L.P .W. ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. 10/005_338						
### Dave T Nguyen 1632		Application No.	Applicant(s)			
Pariod for Raphy A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE £ MONTH(S) FROM THE details of this communication appears on the cover sheet with the correspondence address Period for Raphy A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE £ MONTH(S) FROM THE MAIL MICE DATE OF THIS COMMUNICATION. - Elimentors of lives rapy be available under the previsions of 37 CFR 1.346g.). In on event, however, may a raphy be timely filled after 518. 00 MONTH9 from the mailing date of this communication. - If the period for raphy searched before is lives than they (30) drops, a reply with the statutory and uncernitural (8) MONTH9 from the control part of the reproduction of the communication. - If the period for raphy searched before is lives than the search of the communication of the c		10/005,338	DENEFLE ET AL.			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensive of the reply apendine the provision of 3° CPR¹ 1.35(a), a no event, however, may a reply be limitly flied Extensive of the reply apendined shows is less than thirty (30) days, a reply which the statutory reinfording to five reply appending the one of the communication of	Office Action Summary	Examiner	Art Unit			
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ½ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - after SIX (9) MORTHS from the mailing date of this communication. - if the provide we shall be used to the communication. - if the provide we will be used to the communication. - if the provide the set or extended product of the communication. - if the provide by the Citic and the third the three morting of the provided the spillution to become ABANDONED (St. U.S.C. § 133). - Any reply received by the Citic and that the three morting after the milling date of this communication, even if fitney flict, may seduce any example plant term signature. - Failure to reply within the set or extended prior for reply will. By adults, cause the application to become ABANDONED (St. U.S.C. § 133). - Any reply received by the Citic and that the three membras after the milling date of this communication, even if fitney flict, may seduce any example plant term signature. - Failure to reply within the set or extended prior for reply will. By adults, cause the application, even if fitney flict, may seduce any example plant term signature. - Any reply received by the Citic and the three things the three milling date of this communication, even if fitney flict, may seduce any example plant term signature. - This action is FINAL. - 10] Responsive to communication(s) filled on						
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THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be anabled under the provisions of 37 CFR 1.136(a). In no evert, however, may a reply be timely filed after SIX (8) MCNTHS from the maining date of this communication. If NO portion for reply is pacified above, the maximum statutor, practical and application to become of thirty (30) days will be considered timely. If NO portion for reply is pacified above, the maximum statutor, practical stapple and will septical SIX (8) MCNTHS from the mailing date of this communication. Fallure to reply within this set or extended period for reply will be statuted by the office above, the maximum statutor practical stapple and will septically (8) MCNTHS from the mailing date of this communication, even if timely filed, may reduce any sequences. See 37 CFR 1.74(b). Status 1) Responsive to communication(s) filed on 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-44 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are rejected. 7) Claim(s) is/are rejected to. 8) Claim(s) 1-44 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: al accepted or b) objected to by the Examiner. 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. 12) The eath or declaration is objected to by the Examiner. 12) The proposed drawing correction filed on is: a) approved by the Examiner. 14) Day Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) Acknowledgment is made of a claim fo						
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Restriction to one of the following inventions is required under 35 U.S.C. 121:

Given an enormous number of claimed inventions which were purposely written within each of numerous claims as pending, the exact numbering of each of the claimed inventions required for the restriction will not be listed. However, the restriction requirement as indicated below clearly set forth an invention that can be chosen by applicant for examination.

Claims 1-6, 21-24, 34, 35, 44, are drawn to 122 distinct inventions, wherein each invention is drawn to one particularly named SEQ ID NO: as claimed among SEQ ID NOS: 1-4, and 9-126, vectors, host cells, compositions, and methods of producing the polypeptide by using the particularly named SEQ ID NO:, classifiable in Class 536, subclass 23.5; and Class 435, subclasses 325 and 320.1

Applicant is required to elect one particularly named SEQ ID NO, which corresponds to a particular named gene for examination, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 7, 8, 16, are drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to a ABCA5 probe or primer obtained from a particularly named SEQ ID NO: among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probe or primer must be elected from claim 8 such that the elected probes or primers correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126, which in turns codes for a particular ABCA5. As such, the particularly named SEQ ID NO: and the corresponded probes or primers must be listed in the election. However, the elected probes and primers cannot be greater than 5 sequences. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 7, 9, 16, are drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to a ABCA6 probe or primer obtained from a particularly named SEQ ID NO: among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probe or primer must be elected from claim 9 such that the elected probes or primers correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126, which in turns must code for a particular ABCA6. As such, the particularly named SEQ ID NO: and the corresponded probes or primers must be listed in the election. However, the elected probes and primers cannot be greater than 5 sequences. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 7, 10, 16, are drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to an ABCA9 probe or primer obtained from a particularly named SEQ ID NO: among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probe or primer must be elected from claim 10 such that the elected probes or primers chosen must correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126, which in turns must code for a particular ABCA9. As such, the particularly named SEQ ID NO: and the corresponded probes or primers must be listed in the election. However, the elected probes and primers cannot be greater than 5 sequences. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 7, 11, 16, are drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to an ABCA10 probe or primer obtained from a particularly named SEQ ID NO: among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probe or primer must be elected from claim 11 such that the elected probes or primers chosen must correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126, which in turns must code for a particular ABCA10. As such, the particularly named SEQ ID NO: and the corresponded probes or primers must be listed in the election. However, the elected probes and primers cannot be greater than 5 sequences. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 12 and 14, are drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to a method of employing two primers obtained from a particularly named SEQ ID NO: among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probes or primers must correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126. As such, the particularly named SEQ ID NO: must be listed in the election. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Should an invention be elected according to the immediately preceding paragraph, the elected claimed invention will be treated as a linking claim for one of the inventions chosen from claims 13 and 15 and listed below, which in turns must correspond to the elected claim invention chosen from claims 12 and 14. Note that the restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), as listed above. Upon the allowance of the linking claims, the restriction requirement as to the liked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the

limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 13 and 15, drawn to a plurality of distinct inventions, wherein each of the invention is drawn to a set of two particularly named primers, which in turns must correspond to the elected invention of the linking claims, e.g., claims 12 and 14. The sets of two primer when elected must not exceed 5 sets of primers or probes.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 17-20, drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to a method of employing a primer obtained from a particularly named SEQ ID NO:, which must correspond to an particular named ABC among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probes or primers must correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126. The number of elected probes or primers can not exceed 10 sequences. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 25-28, drawn to 4 distinct inventions of nucleic acids, where each of the invention is drawn to one particularly named SEQ ID NO chosen from SEQ ID NOS: 5-8.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claim 29, 39, drawn to 4 distinct inventions of polypeptides, where each of the invention is drawn to one particularly named SEQ ID NO chosen from SEQ ID NOS: 5-8.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 30-33, drawn to 4 distinct inventions of antibodies, where each of the invention is drawn to an antibody specific against a particularly named SEQ ID NO chosen from SEQ ID NOS: 5-8.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 36, 37, drawn to a plurality of distinct gene therapy methods, which each of the gene therapy invention is drawn to one particularly named SEQ ID NO: as claimed among SEQ ID NOS: 1-4, and 9-126. The elected invention chosen among the plurality of these gene therapy methods can be classifiable in class 514, subclass 44.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claim 38, drawn to a plurality of distinct protein therapy methods, which each of the therapy invention is drawn to one particularly named SEQ ID NO: as claimed among SEQ ID NOS: 5-8. The elected invention chosen among the plurality of these protein therapy methods can be classifiable in class 514, subclass 2.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claim 40-43, drawn to a plurality of distinct protein screening methods, which each of the screening invention is drawn to one particularly named SEQ ID NO: as claimed among SEQ ID NOS: 5-8. The elected invention chosen among the plurality of these protein screening methods can be classifiable in class 435, subclass 7.1.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

The inventions are distinct, each from the other because of the following reasons:

With respect to the nucleic acid claims, the polypeptide claims, the antibody claims, the inventions are directed to products that are district both physically and functionally, and are therefore patentably distinct; and are not required one for the other. For example, the polynucleotides are a fundamentally different type of molecule than the polypeptides, and the polynucleotides can be used in a

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gene therapy method. The proteinsor polypeptides as claimed are structurally distinct from that of antibodies and can be used in treatment of patients having a disease in need of the polypeptides. Thus, these groups are directed to physically and functionally distinct elements, and are therefore patentably distinct; and are not required one for the other.

With respect to claims directed to multiple DNA, protein, or antibody sequences and/or ABC genes, each of the DNA sequences, protein sequences, or antibodies specific to a particular ligand, are drawn to a particularly named sequence with a particular string of nucleotide or amino acid residues. Each of sequences as claimed would code for and/or generate a particular function and/or effect. As such, a search of one particular named sequence would not necessarily overlap with that of another sequence. Furthermore, given a limited resource from the USPTO to conduct a prior art search for multiple sequences as claimed in this application, it would be unduly burdensome to the USPTO to examine and consider fully of the pending claims, which are dawn to an enormous number of sequences. As such and with respect to claims drawn to genes, proteins, or antibodies specific to a ligand, and/or method of use of each, the USPTO only can grant up to one particularly named gene, protein, antibody, or a specifically named SEQ ID NO: for examination. For claims drawn to probes and/or primers, the USPTO only can grant up to 5 specifically sets of two primers or 10 specifically named primers for examination.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because each of the methods of inventions as listed above constitutes patentably distinct inventions for the following reasons: A gene therapy method is not the same as a protein therapy method nor is it the same as a antibody screening assay nor is it the same as that of a protein screening assay. Each of the methods as claimed comprises materially distinct method steps and would generated a distinct function and effect.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper, particularly in view of an undue burden to search and examine of all of the presently pending claims.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. '1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. '1.48(b) and by the fee required under 37 C.F.R. '1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen Primary Examiner Art Unit: 1632

DAVET. NGUYEN PRIMARY EXAMINER